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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,188      | 02/05/2001  | Tomokazu Nagano      | 2520-0120P          | 1286             |

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EXAMINER

BUNNER, BRIDGET E

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1647

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/762,188 | <b>Applicant(s)</b><br>NAGANO ET AL. |  |
|                              | <b>Examiner</b><br>Bridget E. Bunner | <b>Art Unit</b><br>1647              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16,19,20,24,25,28 and 29 is/are rejected.
- 7) ☒ Claim(s) 21,22 and 26 is/are objected to.
- 8) ☒ Claim(s) 1-16,19-26,28 and 29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 03 October 2003 has been entered in full. Claims 16, 19-22, 24-25, and 28-29 are amended and claims 17-18, 23, and 27 are cancelled.

This application contains claims 1-15 drawn to an invention nonelected without traverse in the response of 27 December 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 16, 19-22, 24-26, and 28-29 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

1. The objections to the specification at pg 2-3 of the previous Office Action (03 April 2003) are *withdrawn* in view of the amended specification and title (response of 03 October 2003).
2. The objection to claims 16 and 23 at pg 3 of the previous Office Action (03 April 2003) is *withdrawn* in view of the amended and cancelled claims (response of 03 October 2003).
3. The rejection of claims 16-26 and 28-29 under 35 U.S.C. § 112, first paragraph at pg 3-6 of the previous Office Action (03 April 2003) is *withdrawn* in view of Applicant's persuasive arguments and amendments to the claims (03 October 2003).

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4. The rejection of claims 16-26 and 28-29 under 35 U.S.C. § 112, second paragraph at pg 6 of the previous Office Action (03 April 2003) is *withdrawn* in view of the amended claims (03 October 2003).

5. The rejection of claims 16-25, and 28-29 under 35 U.S.C. § 103 at pg 6-8 of the previous Office Action (03 April 2003) is *withdrawn in part* in view of Applicant's persuasive arguments (03 October 2003). Please see section on Claim Objections and 35 U.S.C. § 103, below.

#### ***Claim Objections***

6. Claim 26 is objected to because of the following informalities:

6a. Claims 21-22, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

7. Claims 16, 19-20, 24-25, and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al. (U.S. Patent 6,498,144) in view of Pu et al. (J Surg Res 54(6): 575-583, 1993). The basis for this rejection is set forth for claims 16-25 and 28-29 at pg 6-8 of the previous Office Action (03 April 2003).

Applicant's arguments (03 October 2003) as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant argues that Pu et al. fails to teach or suggest the deficiencies of Goldberg et al. Applicant asserts that present invention is devised on the basis of the following findings: (1) intramuscular administration of HGF maintains HGF at a high concentration at the

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administration, (2) transportation or action in regions other than the region of illness is small, and (3) a substantial effect is obtained at low dose (specification pg 3-7). Applicant contends that although Pu et al. notes the administration of growth factors locally rather than systemically results in a more beneficial effect, Pu et al. suggests nothing about the superior effectiveness of local administration as compared with systemic administration. Applicant submits that Pu et al. fails to teach or disclose that systemic administration is inefficient compared to direct administration. Applicant argues that Pu et al. teaches nothing about the features of the present invention, that is, HGF by intramuscular administration is maintained at very high concentration at the site of administration, with small transportation or action in other regions other than the region of illness. Applicant asserts that Pu et al. teaches away from the present invention because Pu et al. uses ECGF (not HGF) and recommends increasing the dosage.

Applicant's arguments have been fully considered but are not found to be persuasive. As discussed in the previous Office Action (03 April 2003), Pu et al. teaches that growth factors administered locally rather than systemically have a more beneficial effect (pg 582, ¶ 2).

Although Pu et al. does not teach that systemic administration is not as efficient as compared to direct administration, this recitation is not required by the claims in the instant application.

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The proposed features upon which Applicant is relying would still be obvious to the person of ordinary skill in the art in light of Pu et al. since Pu et al. discloses that the minimal systemic effect of growth factors *in vivo* when they are absorbed into the circulation may result from their short half-life and accumulation in some "filtering" organs in the body, such as the kidney and

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liver (pg 582, ¶ 2). Pu et al. also teaches that pharmacological stimulators are most effective if delivered locally into ischemic tissues (Pu et al., pg 582, bottom of col 1).

Additionally, although Pu et al. does not utilize HGF and recommends increasing the dosage of ECGF, Pu et al. is not teaching away from the present invention. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Goldberg et al. teaches contacting tissue with hepatocyte growth factor (HGF), also known as scatter factor (col 1, lines 33-34; col 8-11). Goldberg et al. teaches that the tissue may be fibrous, endothelial, epithelial, vesicular, cardiac, cerebrovascular, muscular, vascular, transplanted, or wounded (see claims; col 7, lines 6-10). Goldberg et al. discloses that the tissue is ischemic, including myocardial ischemic tissue, cerebrovascular ischemic tissue, and veno-occlusive diseased tissue (see claims; col 13-21). Goldberg et al. also discloses that HGF may be administered to a tissue or subject topically or by intravenous, intramuscular, intradermal, subcutaneous, or intraperitoneal injection in an amount of about 0.1-1000 ng/kg body weight (the bottom of col 4 through the top of col 5).

***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Elizabeth C. Kemmerer*

BEB  
Art Unit 1647  
19 February 2004

ELIZABETH KEMMERER  
PRIMARY EXAMINER